MAR 15 2013

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: March 21, 2009

Applicant:	Arex USA LLC 1709 Hill St. Edgewater, FL 32132
Contact Individual:	Charles Hokanson, Dir. Of Regulatory Affairs 610-715-3263
Trade Name:	X-FIX
Common Name:	External PIP Joint Distraction Device
Regulation Number:	888.3040
Product Code:	HTY
Classification Name:	Pin, Fixation, Smooth
Classification:	Class II
Predicate Device Name:	AREX USA Ligamentotaxor (K094043)
Device Description:	The AREX USA X-FIX is a single use, lightweight, low profile external fixation system designed to treat fractures dislocations of the digits of the hand. The device is designed to help restore proper digit alignment and range of motion while permitting mobilization and normal anatomical movement.

The External Fixation System is as follows:

Description	Reference
X-FIX	X-FIX

Intended Use: The X-FIX is an external fixation system intended for use in the treatment of complex fracture dislocations, stable and unstable dislocations, fracture luxations, and pilon fractures of the PIP joint.

Technology Characteristics: The fundamental scientific technology of the X-FIX is substantially equivalent to the predicate device.

Summary of Design Control Activities:
The materials employed have an established history of biocompatibility and attached medical literature demonstrates that they are non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The design, materials, and indications for use of the Arex USA X-FIX are equivalent to the Arex USA Ligamentotaxor (K094043) previously approved for market in the United States. No new technology has been employed in the design. The Arex USA X-FIX presents no new issues regarding safety and effectiveness

Charles Hokanson Date
Director of Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Arex USA LLC
% Mr. Charles Hokanson
Director of Regulatory Affairs
1709 Hill Street
Edgewater, Florida 32132

Re: K122415
Trade/Device Name: AREX USA X-FIX
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: February 8, 2013
Received: February 25, 2013

Dear Mr. Hokanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122415

Device Name: AREX USA X-FIX

Indications for Use: The X-FIX is an external fixation system intended for use in the treatment of complex fracture dislocations, stable and unstable dislocations, fracture luxations, and pilon fractures in the PIP joint.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices